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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,654	12/29/2000	Sergei G. Bavykin	0003.00797	8872

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/751,654	Applicant(s) BAVYKIN ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' response to the office action (Paper No. 18) filed on February 24, 2003 has been entered and considered.

Response to arguments

2. Applicants' response to the office action (Paper No. 18) is fully considered and found persuasive.

3. With reference to the rejection made under 35 USC 103(a), Applicant's arguments and amendment have been fully considered and the rejection is withdrawn in view of the amendment (Paper No. 15). Applicants' amendment necessitated new grounds of rejection.

New Grounds of Rejections

Non-Statutory Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of copending Application No. 10/057, 753 (Bavykin et al.) in view of Ekenberg (USPN. 6,218,531).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method for labeling genetic material comprising (a) disrupting cells so as to liberate genetic material; (b) contacting the genetic material to a column to immobilized the material; (c) fragmenting and labeling the immobilized genetic material; (d) eluting the labeled material from the column. The instant claims are further drawn to a two-buffer process wherein the first buffer is a lysis buffer to lyse the cells.

The claims of the co-pending application encompass said assay to label the genetic material (see page 11, claims 1-18). However, the co-pending claims did not disclose disrupting the cells to lyse so as to liberate genetic material and use of the lysis buffer.

Ekenberg teaches a method for isolating genetic material wherein the method comprises (i) disrupting cells to liberate genetic material contained in the cells with guanidine isothiocyanate-containing buffer (see column 7, lines 26-40); (ii) contacting the genetic material to a column in a manner to cause the genetic material to become immobilized to the column (anerobic condition) (see column 7, lines 48-52); and eluting the genetic material from the silica column (see column 7, lines 53-65). Ekenberg also teaches more than one buffer system comprising a lysis buffer, dilution buffer, and elution buffer (see column 7, lines 26-42); the process takes less than 1 hour, and more preferably less than 20 minutes (see column 9, lines 14-23); lysis buffer contains guanidine thiocyanate (see column 17, lines 29-35) and elution buffer contains EDTA (see column 16, lines 48-65); pressure is applied to elute the genetic material from the column (see column 20, lines 14-55); the process is maintained between 30- 100 ^{0}C (see column 18 lines 4-23).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of labeling as claimed by Bavykin et al. with a method as taught by Ekenberg to achieve the instant claimed invention as a whole for the expected advantage of developing a method to reduce process time by reducing process steps to achieve isolation and labeling of genetic material in the same process. Therefore, the instant claims are obvious over Bavykin et al. in view of Ekenberg.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirzabekov et al. (USPN. 5,981,734) in view of Ekenberg (USPN. 6,218,531).

Mirzabekov et al. teach a method for labeling genetic material wherein Mirzabekov et al. teach (b, and c) loading the genetic material onto a solid support to immobilize the genetic material (see column 2, lines 39-49) and fragmenting and labeling of the genetic material via creating radical-mediated process at the same time (see column 4, lines 30-67, column 5, lines 1-18); and (d) eluting the labeled genetic material from the column (see column 6, lines 37-52). Mirzabekov et al. also teach (i) contacting double-stranded nucleic acid with radical-generating complexes to produce aldehyde moieties (see column 59-67, column 5, lines 1-14); (ii) reacting the aldehyde moieties with amine to produce condensation product and contacting the codensation product with a chromophore (see column 59-67, column 5, lines 1-14, column 12, lines 35-44) (ii) the labeling of genetic material was carried at temperatures ranging from 20^0 - 37^0 C (see column 6, lines 37-66). Although Mirzabekov et al. teach that the method can be applied to nucleic acid samples extracted from cells (see column 2, lines 29-38), however Mirzabekov et al. specifically did not teach disrupting cells to liberate nucleic acids, and use of two-buffers wherein first buffer is used to lyse the cells.

Ekenberg teaches a method for isolating genetic material wherein the method comprises (i) disrupting cells to liberate genetic material contained in the cells with guanidine isothiocyanate-containing buffer (see column 7, lines 26-40); (ii) contacting the genetic material to a column in a manner to cause the genetic material to become immobilized to the column (anerobic condition) (see column 7, lines 48-52); and eluting the genetic material from the silica column (see column 7, lines 53-65). Ekenberg also teaches more than one buffer system comprising a lysis buffer, dilution buffer, and elution buffer (see column 7, lines 26-42); the process takes less than 1 hour, and more preferably less than 20 minutes (see column 9, lines 14-

23); lysis buffer contains guanidine thiocyanate (see column 17, lines 29-35) and elution buffer contains EDTA (see column 16, lines 48-65); pressure is applied to elute the genetic material from the column (see column 20, lines 14-55); the process is maintained between 30- 100 ^{0}C (see column 18 lines 4-23).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of labeling as taught by Mirzabekov et al with the method of isolating genetic material as taught by Ekenberg because Ekenberg states that "the genetic material obtained from this procedure can be used for analysis or further processing by molecular biological procedures and can also be used for nucleic acid probe hybridization (see page column 17, lines 1-12). Further, selection of specific temperature and buffer ratios represents routine optimization with regard to isolation of genetic material, which routine optimization parameters are explicitly recognized in Ekenberg and Mirzabekov et al. As noted in *In re Aller*, 105 USPQ 233 at 235.More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of specific temperature and ratios of buffer solutions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art. An ordinary practitioner would have been motivated to combine the method of the method of Mirzabekov et al. with the teaching of Ekenberg because the addition of the nucleic acid isolation step using lysis buffer would reduce the process time and improve the method to rapidly isolating and labeling a nucleic acid in one procedure.

B. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proudnikov et al. (Nucleic Acids Res., Vol. 24, No. 22, pp. 4535-4532, 1996) in view of Ekenberg (USPN. 6,218,531).

Proudnikov et al. teach a method for labeling genetic material wherein Proudnikov et al. teach (b, and c) loading the genetic material in a column and fragmenting and labeling of the genetic material in the column via creating radical-mediated process at the same time (see page 4536, column 2, paragraphs 4-5, page 4537, column 1, paragraph 1 and 4538, column 1, and paragraphs 1-6); and (d) eluting the labeled genetic material from the column (see page 4537, column 1, paragraph 1, page 4540, column 2, paragraph 2-3). Proudnikov et al. also teach (i) contacting double-stranded nucleic acid with radical-generating complexes to produce aldehyde moieties (see page 4538, column 1, paragraph 2); (ii) reacting the aldehyde moieties with amine to produce condensation product and contacting the codensation product with a chromophore (see 4538, column 1, paragraph 2, page 4539, column 2, paragraph 2, page 4540, column 1, paragraph 1) (iii) column comprises a syringe for subjecting the column to pressure (see page 4537, column 1, paragraph 1) the labeling of genetic material was carried at temperatures ranging from 20^0 - 37^0 C (see page 4536, column 2, paragraph 3-5, page 4537, column 1, paragraph 2) and the labeling is done in anaerobic (in the column) or aerobic conditions (out side the column or in solution) (see page 4536, column 2, paragraph 4-5, and page 4537, column 1, paragraph 1-2). Although Proudnikov et al. teach that the method can be applied to nucleic acid samples extracted from cells (see page 4541, column 2, paragraph 1), however Proudnikov et al. specifically did not teach disrupting cells to liberate nucleic acids, and use of two-buffers wherein first buffer is used to lyse the cells.

Ekenberg teaches a method for isolating genetic material wherein the method comprises (i) disrupting cells to liberate genetic material contained in the cells with guanidine isothiocyanate-containing buffer (see column 7, lines 26-40); (ii) contacting the genetic material to a column in a manner to cause the genetic material to become immobilized to the column (see column 7, lines 48-52); and eluting the genetic material from the silica column (see column 7, lines 53-65). Ekenberg also teaches more than one buffer system comprising a lysis buffer, dilution buffer, and elution buffer (see column 7, lines 26-42); the process takes less than 1 hour, and more preferably less than 20 minutes (see column 9, lines 14-23); lysis buffer contains guanidine thiocyanate (see column 17, lines 29-35) and elution buffer contains EDTA (see column 16, lines 48-65); pressure is applied to elute the genetic material from the column (see column 20, lines 14-55); the process is maintained between 30- 100 ^{0}C (see column 18 lines 4-23).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of labeling genetic material as taught by Proudnikov et al. with the method of isolating genetic material as taught by Ekenberg because Ekenberg states that "the genetic material obtained from this procedure can be used for analysis or further processing by molecular biological procedures and can also be used for nucleic acid probe hybridization (see page column 17, lines 1-12). Further, selection of specific temperature and buffer ratios represents routine optimization with regard to isolation of genetic material, which routine optimization parameters are explicitly recognized in Ekenberg and Proudnikov et al. As noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of specific temperature and ratios of buffer solutions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art. An ordinary practitioner would have been motivated to combine the method of the method of Proudnikov et al. with the teaching of Ekenberg because the addition of the nucleic acid isolation step using lysis buffer would reduce the process time and improve the method to rapidly isolating and labeling a nucleic acid in one procedure.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
May 15, 2003

JEFFREY FREDMAN
PRIMARY EXAMINER